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EXAMINER

WEDDINGTON, KEVIN E

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ROLF JOACHIM MEHLHORN

Appeal 2010-010938
Application 10/759,222
Technology Center 1600

Before DONALD E. ADAMS, DEMETRA J. MILLS, and
STEPHEN WALSH, *Administrative Patent Judges*.

WALSH, *Administrative Patent Judge*.

DECISION ON APPEAL¹

This is an appeal under 35 U.S.C. § 134(a) involving claims to methods of loading lipid-like vesicles, kits for loading lipid-like vesicles, and a method of detoxifying an animal suffering from an overdose of a

¹ The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the “MAIL DATE” (paper delivery mode) or the “NOTIFICATION DATE” (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

chemical species by injecting the animal with a solution of liposomes. The Patent Examiner rejected the claims as obvious and on the ground of non-statutory obviousness-type double patenting. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

Claims 1-12 and 16-23 are on appeal. Claim 1 is representative and reads as follows:

1. A method of loading lipid-like vesicles, comprising:
forming lipid-like vesicles in a solution comprising an acidic buffer if the chemical species to be loaded is basic or a basic buffer if the chemical species to be loaded is acidic; wherein:
membranes of the formed lipid-like vesicles are impermeable to the buffer; adjusting the pH of the solution exterior to the membranes of the lipid-like vesicles to a basic pH if the chemical species to be loaded is basic or to an acidic pH if the chemical species to be loaded is acidic;
adding a basic chemical species to the adjusted basic exterior solution or an acidic chemical species to the adjusted acidic exterior solution;
loading the chemical species into the vesicle; and
adjusting the exterior solution to a physiologically benign pH; wherein:
the chemical species is substantially maintained in the vesicle for at least one quarter hour after the adjustment of the exterior solution.

The Examiner rejected the claims as follows:

- claims 1-12 under 35 U.S.C. § 103(a) as unpatentable over Nichols,² or Deamer,³ or Cramer;⁴ and

² J. Wylie Nichols et al., *Catecholamine Uptake and Concentration by Liposomes Maintaining pH Gradients*, 455 BIOCHIM. BIOPHYS. ACTA, 269-271 (1976).

- claims 16-23 on the ground of non-statutory obviousness-type double patenting as unpatentable over claims 1-7 of Mehlhorn.⁵

Claims 2-12 and 16-23 have not been argued separately and therefore stand or fall with claim 1. 37 C.F.R. § 41.37(c)(1)(vii).

OBVIOUSNESS

The Issue

The Examiner's position is that Nichols and Deamer each teach a method of preparing liposomes using the instantly claimed method. (Ans. 5-6.) Specifically, the Examiner found that Nichols and Deamer disclosed preparing liposomes with an acidic pH and titrating them with a base to create a pH gradient, then loading the liposome with a basic chemical species, such as epinephrine in Nichols and a basic amine in Deamer. (*Id.*) The Examiner reasoned that although Nichols and Deamer did not teach establishing the pH gradient by the addition of an acid, it would have been understood and within the skill of the art to do so when the internal medium is basic. (*Id.*) According to the Examiner, it would have been obvious to a skilled artisan at the time of the invention to load a lipid-like vesicle with

³ David W. Deamer et al., *The Response of Fluorescent Amines to pH Gradients Across Liposome Membranes*, 274 BIOCHIM. BIOPHYS. ACTA, 323-335 (1972).

⁴ John A. Cramer et al., *NMR Studies of pH-Induced Transport of Carboxylic Acids Across Phospholipid Vesicle Membranes*, 75 BIOCHEM. BIOPHYS. RES. COMM., NO. 2, 295-301 (1977).

⁵ Rolf Joachim Mehlhorn, US Patent No. 5,762,957, issued Jun. 9, 1998.

any drug with an expectation of success since Nichols and Deamer taught the principle of loading. (*Id.*)

The Examiner found that Cramer also taught a method of preparing “liposomes and lowering the pH of the external medium.” (*Id.* at 6.) The Examiner found that Cramer disclosed loading its liposomes with acidic compounds. (*Id.*) The Examiner reasoned that although Cramer did not teach establishing the pH gradient by adding an acid, doing so would have been understood and within the skill in the art when the internal medium was basic. According to the Examiner, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to load a lipid-like vesicle with any drug with an expectation of success since Cramer taught the principle of loading. (*Id.* at 6-7.)

Appellant does not dispute that Nichols disclosed loading an amine into a liposome using a pH gradient. (App. Br. 10.) However, Appellant contends that “Nichols says nothing whatsoever about what happens to the loaded material after loading.” (*Id.*). According to Appellant, the claimed method provides that the concentration of the loaded chemical can be maintained in the lipid-like vesicle “for a substantial period of time after the pH gradient has been destroyed ... [which] is an unexpected, surprising, utterly novel development that in no way could have been gleaned from Nichols by those skilled in the art.” (*Id.*) Appellant asserts that neither Deamer nor Cramer suggest this result either. (*Id.* at 10; Reply Br. 3)

The issues with respect to this rejection are:

whether the record supports the Examiner’s conclusion that the cited prior art would have made the claimed methods of loading lipid-like vesicles *prima facie* obvious, and if so,

whether Appellant has provided evidence of unexpected results such that the totality of evidence weighs in favor of nonobviousness.

Findings of Fact

1. We agree with the Examiner's explicit findings regarding the scope and content of the prior art references. (*See* Ans. 5-7.)

Principles of Law

"Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention." *In re Baxter Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991).

It is well settled that unexpected results must be established by factual evidence. Mere argument or conclusory statements in the specification does not suffice. *In re Lindner*, 457 F.2d 506, 508 (CCPA 1972).

Analysis

We are not persuaded by Appellant's assertion that the claimed method of loading lipid-like vesicles is not obvious over the prior art because the prior art did not disclose or suggest that the chemical species loaded in the vesicle, or liposome, "is substantially maintained in the vesicle for at least one quarter hour after the adjustment of the exterior solution," as recited in the claims.⁶ Such recognition of a latent property of the prior art

⁶ We have only considered arguments that Appellant raised in the Briefs. Arguments that Appellant could have raised, but chose not to raise, have not been considered and are deemed to be waived. See C.F.R. § 41.37 (c)(1)vii).

methods does not, by itself, render the claimed invention nonobvious. *See Baxter-Travenol Labs.*, 952 F.2d at 392.

Although Appellant asserts that this property is an unexpected and surprising development (App. Br. 10; Reply Br. 3) Appellant has not established this position with any factual evidence. *See Lindner*, 457 F.2d at 508.

Accordingly, we affirm the obviousness rejection of claims 1-12.

NON-STATUTORY OBVIOUSNESS-TYPE DOUBLE PATENTING *Analysis*

Appellant does not challenge the Examiner's rejection of claims 16-23 on the ground of non-statutory obviousness-type double patenting as unpatentable over claims 1-7 of Mehlhorn. (*See* Reply Br. 4.) Rather, Appellant states that "Applicant is prepared to submit a terminal disclaimer disclaiming any term of a patent that issues based on the instant application should such terminal disclaimer be all that stands between this applicant and issuance." (*Id.*)

Accordingly, we affirm the rejection.

CONCLUSIONS OF LAW

The record supports the Examiner's conclusion that the cited prior art would have made the claimed methods of loading lipid-like vesicles *prima facie* obvious, and Appellant has not provided evidence of unexpected results such that the totality of evidence weighs in favor of nonobviousness.

Appellant has not established that the claimed kits for loading lipid-like vesicles and method of detoxifying an animal suffering from an overdose would have been nonobvious over claims 1-7 of Mehlhorn.

SUMMARY

We affirm the rejections of claims 1-12 under 35 U.S.C. § 103(a) as unpatentable over Nichols, or Deamer, or Cramer; and

we affirm the rejection of claims 16-23 on the ground of non-statutory obviousness-type double patenting as unpatentable over claims 1-7 of Mehlhorn.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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